REMARKS

Claim 1, 11, and 12 have been amended to specify that the claimed terpolymers consist of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone. Claim 12 has been further amended to clarify that the terpolymer is a moldable putty. New claims 13-18 are similar to original claims 5-10, with new claims 13, 14, and 16 being written in independent form. No new matter is added by way of any of these amendments.

Claims 1-3, 11, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brine (U.S. Patent No. 5,075,115). Specifically, the Examiner contends that Brine teaches polymers of lactic acid with a molecular weight of 2500-4500, specifies terpolymers with other hydroxycarboxylic acids such as glycolic acid, ε- caprolactone and valerolactone (column 3, lines 28-32), and discloses glass transition temperatures of 26°C to -65°C (column 3, lines 52-53). Applicants respectfully traverse that rejection. The Examiner contends that Brine teaches polymers of lactic acid with a molecular weight of 2500-4500, and specifies that these polymers have glass transition temperatures of 26°C to -65°C. However, Brine does not describe lactide-containing terpolymers consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone, as required by claims 1-3, 11, and 12. Therefore, the rejection based on Brine is believed to be improper.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The Examiner contends that Brine teaches terpolymers of lactic acid with other hydroxycarboxylic acids. Respectfully, Brine makes no mention whatsoever of terpolymers. Rather, Brine teaches poly(lactic acid) mixed with copolymers/homopolymers of other hydroxycarboxylic acids. The specification of Brine states

that "the present invention is a process for polymerizing lactic acid to poly(lactic acid) . . . the present invention is intended to include the product made by the process as well as copolymers and mixtures of polymers of glycolic acid, valerolactone, ε- caprolactone, ε- decalactone, hydroxybutyric acid, β- hydroxyvaleric acid and dioxanone . . ." (see column 3, lines 5-32). Notably, Brine's Examples 1 and 2 teach a blend of a poly(DL-lactic acid) polymer and a polycaprolactone polymer, and Table 1, entitled "Polymer Overview," teaches only poly(L-lactic acid), poly(DL-lactic acid), and polycaprolactone polymers. Thus, the teachings of Brine are directed to polymers formed from poly(lactic acid) precursors rather than to terpolymers consisting of monomer units as required by the present claims.

A terpolymer is a polymer made from three monomers. While there is some suggestion in Brine of copolymers, there as absolutely no suggestion in Brine to use three different monomers, let alone the particular terpolymers of poly(lactide/glycolide/caprolactone) or poly(lactide/glycolide/valerolactone). Moreover, while Brine teaches polymers made from poly(lactic acid) and other hydroxycarboxylic acids, poly(lactic acid) is by definition a polymer, not a monomer. Thus, Brine teaches poly(lactic acid) polymeric components of molecular weight 2500 to 4500 mixed with homopolymers/copolymers of other hydroxycarboxylic acids. A required element of the invention of claims 1-3, 11, and 12 is a lactide-containing terpolymer consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone. Thus, the claimed invention requires that the polymers contain lactic acid, glycolic acid, and caprolactone or valerolactone monomer units. Respectfully, Brine cannot be said to anticipate claims 1-3, 11, and 12.

Furthermore, claims 1-3, 11, and 12 specify that the claimed terpolymers exhibit an "adhesive strength of about 600 to about 150,000 Pa" such that they can be used as pressure

sensitive adhesives for tissue repair. Brine discloses the use of poly(lactic acid) in dosage forms for the controlled release of pharmaceutically active compounds. Brine is silent on the characteristics of the disclosed poly(lactic acid) compositions. Notably, Applicants' sticky polymers would complicate (gum up the machine) the tableting of, for example, tableting compositions used to prepare tableted controlled release dosage forms. Further, the polymer compositions taught by Brine (to be used as taught by Brine) necessarily have properties different than the polymers of the present invention. Therefore, Brine cannot reasonably be said to anticipate claims 1-3, 11, and 12.

In sum, Brine (U.S. Patent No. 5,075,115) does not describe lactide-containing terpolymers consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone, nor does the reference describe or suggest such polymers capable of functioning as pressure sensitive adhesives for tissue repair. Brine, therefore, cannot reasonably be said to anticipate claims 1-3, 11, and 12. Withdrawal of the rejection of claims 1-3, 11, and 12 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1-2, 11, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by English et al. (U.S. Patent No. 4,804,691). Specifically, the Examiner contends that English et al. teaches a polyester of molecular weight 500-10000 (column 2, line 68 through column 3, line 2) and specifies copolymers of lactide, glycolide, and caprolactone (column 3, lines 14-16). Applicants respectfully traverse the Examiner's rejection under 35 U.S.C. § 102(b).

Applicants have amended claims 1-2, 11, and 12 to specify a lactide-containing terpolymer consisting of monomer units selected from the group consisting of lactic acid, glycolic acid and caprolactone or valerolactone. English et al. teaches a method for making an

adhesive in which the first step is to prepare a hydroxyl-terminated polyester by reacting a biodegradable monomer with a polyhydroxy polymerization initiator (see Abstract and column 3, lines 3-6). Accordingly, both the polymers prior to end capping with diisocyanate (*i.e.*, the intermediate polymer referred to by the Examiner) and the polymers having diisocyanate end caps contain polyhydroxy polymerization initiators. Amended claims 1-2, 11, and 12 specify terpolymers consisting of monomer units selected from the group consisting of lactic acid, glycolic acid and caprolactone or valerolactone, thereby excluding polymerization initiators. A required element of the invention of claims 1-2, 11, and 12 is terpolymers consisting of lactic acid, glycolic acid, and caprolactone or valerolactone. English et al. does not describe this required element, and, respectfully, cannot be said to anticipate claims 1-2, 11, and 12.

Furthermore, claims 1-2, 11, and 12 are directed to a thermoplastic terpolymer. "Thermoplastic" terpolymers are inherently non-reactive. The polyester backbone of the English et al. compounds has terminal diisocyanate groups (column 3, lines 3-13 and claims 1-21). The very purpose of those reactive groups are to provide bis-functional components that will react with and form covalent bonds with isocyanate-reactive groups. The terminal diisocyanate groups on the polyesters described in English et al. are inherently reactive with compounds having isocyanate reactive groups, thereby providing a reactive thermosetting composition, rather than the presently claimed thermoplastic adhesive (without such reactive groups). Respectfully, English et al. does not anticipate the invention of claims 1-2, 11, and 12.

Additionally, claims 1-2, 11, and 12 specify a pressure sensitive adhesive with "an average molecular weight of 1,000 to 3,000" exhibiting "an adhesive strength of about 600 to about 150,000 Pa," and with a "water solubility of 0.01 to about 500 mg/ml at about 25°C." English et al. contains no exemplified teaching of an adhesive with an average molecular weight

of 1,000 to 3,000. In fact, each of the exemplified adhesives taught in Table I and II have molecular weights of 5,000 or 10,000. Furthermore, English et al. does not mention "an adhesive strength of about 600 to about 150,000 Pa" or a "water solubility of 0.01 to about 500 mg/ml at about 25°C." Thus, neither the polymer disclosed in English et al. prior to end capping with diisocyanate nor the polymer having diisocyanate end caps anticipates the invention of claims 1-2, 11, and 12. Withdrawal of the rejection of claims 1-2, 11, and 12 under 35 U.S.C. § 102(b) in view of English et al. is respectfully requested.

Claims 1-2, 11, and 12 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Storey et al. The Examiner contends that Storey et al. teaches the polymerization of lactide, glycoside, and caprolactone monomers, and that a molecular weight of 2700 is specified. Storey et al. teaches polymers made using polyol initiators. The "consisting of" language in the claims precludes polymers made with any components other than lactic acid, glycolic acid, and caprolactone or valerolactone. Therefore, Storey et al. does not anticipate the present claims. Withdrawal of the rejection of claims 1-2, 11, and 12 under 35 U.S.C. § 102(a) is respectfully requested.

Claim 4 stands rejected under 35 U.S.C. § 101 as claiming the same invention as claim 1 of U.S. Patent No. 6,299,905. Claim 4 depends from claim 1, which has been amended to specify a terpolymer consisting of monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone. Because of the amendment to claim 1, applicants submit that claim 4 is no longer directed to the same invention as claim 1 of the '905 patent. Applicants respectfully request withdrawal of this rejection.

Claims 1-12 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.

6,299,905. Enclosed is a terminal disclaimer under 37 C.F.R. § 1.321(b), disclaiming any term beyond the expiration date of U.S. Patent No. 6,299,905. Withdrawal of the double patenting rejection is respectfully requested.

Finally, claim 12 has been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner contends that the term "provided as a putty" is vague. Claim 12 has been amended to clarify this term. Applicants respectfully request withdrawal of this rejection.

CONCLUSION

The application as amended, is believed to be in condition for allowance. Withdrawal of the rejections and passage of the application to issuance is requested.

Respectfully submitted,

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Appendix A
Version with markings to show changes made

Under 37 C.F.R. § 1.121(c)(1)(i), please amend claims 1, 11, and 12 as follows:

1. (Amended) A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting ~~of monomer units derived from~~ lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa, and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.

11. (Amended) A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 2,500, exhibiting an adhesive strength of about 600 to about 150,000 Pa and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.

12. (Amended) A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer being [provided as] a moldable putty, having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.